Karbiwnyk vs. R.J. Reynolds 10/23/97 1:00 p.m. - 2:50 p.m. ROUGH DRAFT 1 2 JOANN KARBIWNYK, 3 Plaintiff, 4 vs. R. J. REYNOLDS TOBACCO COMPANY 5 6 Defendant. 7 8 9 Thursday, October 23, 1997 10 Judge Michael Weatherby 11 Courtroom 2 12 13 APPEARANCES: 14 NORWOOD WILNER, Esquire, GREG MAXWELL, Esquire, and STEPHANIE HARTLEY, Esquire, Attorneys 15 16 for Plaintiff. 17 THEODORE GROSSMAN, Esquire, JAMES YOUNG, 18 19 Esquire, DIANE G. PULLEY, Esquire, and 20 DENNIS MURPHY, Esquire, Attorneys for R. J. 21 Reynolds. 22 23 24 25 3451 Karbiwnyk vs. R.J. Reynolds 10/23/97 1:00 p.m. - 2:50 p.m. ROUGH DRAFT

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PROCEEDINGS

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2
     Thursday, October 23, 1997
                                                 1:00 p.m.
 3
 4
               (The following proceedings were reported by
 5
     Deanne Ferreira:)
              MS. PULLEY: Line 12.
 6
 7
              MR. KITCHEN: 3 to 12.
              MR. MAXWELL: 3 to 12?
 8
 9
              THE COURT: On the same page?
              MR. MAXWELL: Yes, sir.
10
11
              MS. PULLEY: That's merely identifying
          Betty as her sister and that Betty was against
12
13
         smoking.
14
              THE COURT: Okay.
              MR. MAXWELL: My argument, Judge --
15
              THE COURT: Don't tell me. I understand
16
         your argument, just tell me --
17
              MS. PULLEY: Page 63, lines 8 to 12.
18
19
              THE COURT: Say again?
              MS. PULLEY: Page 63, lines 8 to 12.
20
              THE COURT: 63, 8 through 12.
21
              MS. PULLEY: And continuing at line 17 --
22
          if you want to just consider the whole thing
23
24
         beginning page 63 line 8, all the way through
         page 65 line 16. Well, actually it goes --
25
                                                     3452
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          actually I'd stop -- for this particular
 1
 2
          objection, I think you should stop at page 64,
 3
          line 23.
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MR. MAXWELL: Well, you know, I don't mean 5 to be quibbling, but I really -- you know, I formulated my objections based upon specific 6 7 portions that you identified. MS. PULLEY: Yeah. I was just stopping --8 65 is the Raleigh coupon, I assumed that's a 9 different objection than the family smoking. 10 MR. MAXWELL: They overlap. 11 MS. PULLEY: You can do the whole thing 12 13 then. 63, line 8 through page 64, line 4. THE COURT: I'm sorry, say that again, 14 Diane. 15 MS. PULLEY: Page 63, line 8 through page 16 66, line 4. 17 THE COURT: Okay. All right. And? 18 19 MR. MAXWELL: Page 67, line 10. MS. PULLEY: I thought you were going to 20 reconsider the fertility pills. 2.1 MR. MAXWELL: I'm sorry,, I'm sorry. 22 THE COURT: That's already in --23 24 MR. MAXWELL: I'll withdraw my objection to 25 that. 3453 Karbiwnyk vs. R.J. Reynolds 10/23/97 1:00 p.m. - 2:50 p.m. ROUGH DRAFT 1 MS. PULLEY: Okay. 2 MR. MAXWELL: We don't have to worry about that. So then we go to, what, 71? 3 4 MS. PULLEY: Yeah. Which you were also 5 going to reconsider.

4

6

MR. MAXWELL: Let's -- which line are we

7 talking about? 8 MS. PULLEY: Lines 6 through 24 on page 9 71. We merely want -- wanted to introduce this 10 evidence so later on we could potentially arque that she had a change in lifestyle, not that she 11 quit smoking. 12 13 MR. MAXWELL: I'm sorry, page 6 through 24? 14 MS. PULLEY: Line 6 through 24. MR. MAXWELL: Okay. I'll withdraw my 15 16 objection to that. MS. PULLEY: Okay. And I believe that's 17 18 it, Your Honor, in terms of any issues. 19 MR. MAXWELL: Wait. Wait. Let's see. You -- let's make sure. You withdrew to 20 21 the 72, 74, then we went to -- and page 78, lines 5 through 16. Let me take a quick look at 2.2 that. 23 2.4 MS. PULLEY: I'm sorry, page 78? 25 MR. MAXWELL: Page, 78 lines 5 through 17. 3454 Karbiwnyk vs. R.J. Reynolds ROUGH DRAFT 10/23/97 1:00 p.m. - 2:50 p.m. 1 MS. PULLEY: 78, I withdrew the whole page. 2 MR. MAXWELL: Okay. 3 MS. PULLEY: Except questions 11 and 12. 4 MR. MAXWELL: Let me see. Yes, that's 5 fine. Okay. That -- that I think does it. MS. PULLEY: However, Your Honor, we had 6 7 one objection to their counter designations, if

you still wanted to --

9	MR. MAXWELL: Yeah. Yeah. Let's take that
10	up.
11	MS. PULLEY: What page was that on?
12	MR. MAXWELL: That is on page 86 right
13	at the very end. Page 88, line 14 to page 89,
14	line 2, which is what I wanted to read.
15	THE COURT: 88/14?
16	MR. MAXWELL: Yes, Your Honor.
17	THE COURT: To
18	MR. MAXWELL: 89, line 2. That's the only
19	objection you had to mine, right?
20	MS. PULLEY: Right. Your Honor, we feared
21	it would be prejudicial to the defense to have
22	this read in because it sounds like we were
23	badgering this woman asking her about her legal
24	drug use. The fact that she has no illegal drug
25	use makes it irrelevant to the case. However,
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1	had she had drug use during the period, that
2	could have been potentially relevant and
3	appropriate for a discovery deposition.
4	MR. MAXWELL: Well, it establishes that she
5	didn't use any illegal drugs.
6	MS. PULLEY: That's not an issue in this

THE COURT: When did that become an issue?

MR. MAXWELL: Well, Your Honor, they've

talked a lot of different risk factors and they

asked the questions. I think it's -- it's

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10

11

case.

12	evidence that this witness who knew her very
13	well denies that she ever engaged in any other
14	sort of risky behavior.
15	THE COURT: Why is that any less
16	objectionable than the defense's objection that
17	[DELETED] should be admissible?
18	MR. MAXWELL: You may have a point there,
19	Your Honor. I just like it. It sounds good,
20	makes my client sound good.
21	THE COURT: What's that phrase, what's good
22	for the goose is good for the gander.
23	MR. KITCHEN: I need to make a response on
24	this record before we stop, so whenever we get
25	to that.

3456 Karbiwnyk vs. R.J. Reynolds 10/23/97 1:00 p.m. - 2:50 p.m. ROUGH DRAFT MR. MAXWELL: I'll withdraw that. 1 2 MR. KITCHEN: I have one thing to add that I didn't respond to. 3 MR. MAXWELL: Before we do that --THE COURT: Is that all the transcript? 5 MR. MAXWELL: Yes, Your Honor. And I have 7 withdrawn that one portion I was going to read, so I'll delete that. 9 THE COURT: I won't worry about that. 10 MR. KITCHEN: Even looking at consumer 11 expectation as a -- an objective standard, this 12 court has said previously in hearings here that

13

what the plaintiff knows is part of common

14	knowledge and what the plaintiff knows is
15	evidence of common knowledge, and to try to
16	eliminate anything she knew in a consumer
17	expectation question and a failure to warn is
18	is fundamental error.
19	MR. MAXWELL: Well, you know, I think they
20	want to be able to argue that her testimony is
21	proof of consumer expectation, and the Hobart
22	versus Seigler case, I think, clearly puts that
23	to rest, that's an objective test.
24	Now, Your Honor, the the the
25	portions that we've identified that I have

3457 Karbiwnyk vs. R.J. Reynolds 10/23/97 1:00 p.m. - 2:50 p.m. ROUGH DRAFT objections to, all of them have that basic 1 2 objection that it goes to her knowledge. However, I also have objections, and I 3 4 think you will, as you read them, the testimony, 5 you'll see I have objections to hearsay. THE COURT: Uh-huh. 6 MR. MAXWELL: For example, there's a portion where he says the mother said something. 8 THE COURT: Yeah, I saw that. MR. MAXWELL: And let me just make sure, I 10 don't want to waive any -- also some of these --11 12 some of the portions of the testimony, especially the -- the husband's testimony, is 13 14 vague as to time. There's no -- there's no indication as to when he says she knew certain 15 things and -- and that goes -- that's also --16

17	THE COURT: But he does say when they were
18	divorced, doesn't he?
19	MR. MAXWELL: He says they were divorced in
20	1987, they continued to have contact
21	MR. KITCHEN: '79.
22	MR. MAXWELL: I'm sorry, did I say '87?
23	'79. But they continued to have contact
24	because they had a child together, so it's vague
25	as to time. And the mother, as well, there's no
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1	indication there with respect as to what the
2	mother said as to when they claimed what she
3	said.
4	So I do have I just want the record to
5	reflective other objections as well to but
6	the the common thread that runs through all
7	this is that we we just don't think that
8	that they should be permitted to try what is
9	essentially an assumption of the risk case
10	unless we get apportionment.
11	THE COURT: Okay. I'll
12	MR. KITCHEN: And we simply say you can't
13	take the plaintiff out of this case.
14	MR. MAXWELL: And, you know, I'll agree to
15	that to a certain extent. You know, sometimes
16	there are there are are
17	are are facts that are sort of part of the
18	res gestae that are just there. But it's

19	another matter to to produce extrinsic
20	evidence to come in and and prove up a
21	collateral issue.
22	And that's our position, this is a
23	collateral issue now because they've withdrawn
24	the comparative. Her knowledge is is
25	collateral.

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1 And even though it might come out in a case 2 because it's just part of the case, it doesn't 3 -- it shouldn't be tried and it shouldn't be argued. And, Your Honor, in the last case in 5 the closing argument we got killed. They stood up and said she -- in the face of all the 6 7 evidence that smoking was dangerous, she continued to smoke. She chose to continue to smoke, that's assumption of risk. 9 10 THE COURT: They're going to say that any way. Even if I sustain your objection, what 11 12 else are they going to say? MR. MAXWELL: Well, I think that's 13 improper. I think it's improper to argue that 14 the conduct of the plaintiff was negligent or 15 was contributing to the injury when we don't get 16 17 apportionment. And that's what comparative negligence is all about, is not defeating a 18 plaintiff's claim by -- by making it all or 19 20 nothing.

MR. KITCHEN: For them to put on a prima

22	facie case, they've got to put on the evidence
23	that the warning would have changed and that it
24	wasn't commonly known in consumer expectation.
25	In order for them to put on a prima facie case.
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1	MR. MAXWELL: No. No. The consumer
2	expectation, we don't have to prove consumer
3	expectation. That's an element. That's one of
4	the factors the courts considered. We could not
5	put on anything about consumer expectation and
6	still have a case admissible to a jury. Because
7	if you look at the factors of consumer
8	expectation, there's only one of the five or six
9	factors out of the strict liability test that
10	Your Honor may recal.
11	MR. KITCHEN: No, that's under the second
12	that's under the alternative test, not under
13	the first one.
14	MR. MAXWELL: Well, you've raised it as a
15	defense and we can respond to it. But we don't
16	have to put it on.
17	MR. KITCHEN: We've been trying these cases
18	for three weeks on these theories and they still
19	ought to be in this case. That's all I've got,
20	Judge.
21	THE COURT: Well, once again, no matter
22	what I do, we'll be making law. I'll let you
23	know when we come back.

24 MR. MAXWELL: You have to admit -- we can 25 go off the record. 3461 Karbiwnyk vs. R.J. Reynolds 10/23/97 1:00 p.m. - 2:50 p.m. ROUGH DRAFT 1 (Short recess.) 2 THE COURT: Mr. Kitchen, Mr. Maxwell, do you need to know right now on that matter? 3 MR. KITCHEN: No, sir, not until we go to 5 publish later. MR. MAXWELL: Your Honor --THE COURT: I need -- I want to -- I'd 7 rather not rule at the moment, if that's all 8 9 right. 10 MR. MAXWELL: That's fine. THE COURT: Okay. All right. We are 11 here. Mrs. Karbiwnyk is coming? 12 MR. WILNER: On her way. I think we can 13 start. 14 15 THE COURT: All right. Bring out the 16 jury. 17 (The jury was seated in the jury box and 18 the following was held in open court:) THE COURT: The jury has returned. Be 19 20 seated, Ladies and Gentlemen. Mr. Wilner? 21 CROSS EXAMINATION (Cont'd) 22 BY MR. WILNER: Q Dr. Wicker, I have only a few more 23 questions for you. 24

A I'm Dr. Thomas.

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- 1 Q Dr. Thomas, thank you. Who did I call
- 2 you? Someone else?
- 3 A Yes.
- 4 Q I'm sorry, I'm getting tired here today. I
- 5 appreciate you correcting me.
- 6 Dr. Thomas, you just -- we just talked
- 7 about the -- the -- this business about air
- 8 pollution, and -- or a little bit about it. Did I --
- 9 will you clarify why when you were asked about
- 10 cigarette smoking, you always said there's been a
- 11 reduction in risk because of the 10 years or 11 years
- 12 since Joann stopped smoking, but never mentioned that
- 13 about the air pollution?
- 14 A I don't think I mentioned about either one,
- 15 except talking specifically about her medical
- 16 records. It's -- I would expect it's the same type
- 17 of knowledge concerning a pollutant that's inhaled,
- 18 whether it's air pollution or cigarette smoke that
- 19 would be cleared from lungs over time.
- 20 Q Would you -- are you familiar with the 1989
- 21 surgeon general's report on ambient air pollutants,
- 22 which includes a section on ambient air pollution?
- 23 A Yes, I am.
- Q And the surgeon general's report is
- 25 entitled Reducing the Health Consequence of Smoking,

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- 1 20 Years of Progress, a report of the surgeon general
- 2 1989; you're familiar with that?
- 3 A Yes, I am.
- 4 Q Let me ask you if you agree or disagree.
- 5 On page 53, it says, ambient air pollution, the 1964
- 6 report noted that lung cancer mortality rates tended
- 7 to be higher in urban areas than in rural locations.
- 8 Air pollution was considered a plausible explanation
- 9 for these differences. The association of lung
- 10 cancer with atmospheric pollution derives biologic
- 11 plausibility from the presence of carcinogens in
- 12 polluted air and has some support in the
- 13 epidemiologic --
- 14 A Excuse me. Is there a possibility I can
- 15 actually see what you're reading while you're reading
- 16 it?
- 17 Q I'm reading from the surgeon general
- 18 report, and I'll have to put it on the monitor for
- 19 you.
- 20 A If I can get up and look at the monitor?
- 21 THE COURT: Sure.
- 22 Q Yes, you can. I was reading here. The
- 23 association of lung cancer with atmospheric pollution
- 24 derives biological plausibility from the presence of
- 25 carcinogens in polluted air and has some support from

- 1 epidemiologic data. However, epidemiologic
- 2 investigation of ambient air pollution as a risk

- 3 factor for lung cancer has been hampered by
- 4 methodological problems, including the necessity of
- 5 considering cigarette smoking and the difficulty of
- 6 assessing pollution exposure.
- 7 Recent epidemiologic investigations have
- 8 not shown strong effects of air pollution, citing
- 9 Samok 1987, Buffer, 1988, and Doll and Pena 1981.
- 10 In their review of the cause of cancer
- 11 estimated that only one or two percent of lung cancer
- 12 was related to air pollution. Do you see that?
- 13 A Yes, I do.
- 14 Q Do you agree or disagree?
- 15 A I agree at the time that -- that was the
- 16 situation. As they pointed out in this paragraph,
- 17 they were hampered by methodological problems, some
- 18 of those we've been able to work through now, and so
- 19 we've gotten better estimates than were found by the
- 20 National Institute of Health in 1986, which is what
- 21 this is referring to.
- Q Well, Doctor --
- 23 A So that's almost 10 years ago.
- Q Well, produce what you think is better.
- 25 A I'm sorry?

- 1 Q Produce what you think is better.
- 2 A I think most people agree now that
- 3 epidemiologic studies do show a strong association
- 4 with air pollution, and that the risks we can now

- 5 calculate just as -- were done in this EPA report we
- 6 looked at this morning. In fact, this refers to some
- 7 familial studies that John and Samot studied, I don't
- 8 know whether that helped them or not. And the Doll
- 9 and Pena study it's talking with is 1981 which
- 10 actually is quite a while ago for the development of
- 11 scientific methodology, so some of the things stated
- 12 in this paragraph have now been taken care of 10
- 13 years later.
- 14 Q Produce it, Doctor.
- 15 THE COURT: Mr. Wilner.
- 16 Q Can you?
- 17 MR. YOUNG: Your Honor, is he asking us to
- recess the court to go get documents?
- MR. WILNER: I'll rephrase.
- 20 BY MR. WILNER:
- 21 Q Do you have it in front of you? Can you
- 22 produce it?
- 23 A I don't have it in front of me.
- Q Can you tell us what it is?
- 25 A I can tell you to what led to the changes

- 1 and how the changes have been made.
- 2 Q Can you give us a study, or a note that
- 3 you've got or anything that substantiates what you
- 4 say?
- 5 A Yes. The report that I directed at the
- 6 National Academy of Sciences in 1994 called Science
- 7 and Judgment, Risk Assessment. It's 800 pages that

- 8 deal with methodological development, including how
- 9 to do these types of estimates, and that specifically
- 10 directs EPA how to do them under the Due Clean Air
- 11 Act.
- 12 Q And so if -- if the number by the surgeon
- 13 general was one to two percent, what's your number?
- 14 A Let me look at it again.
- 15 Q One to two percent of lung cancer citing
- 16 Doll and Pena, what's your number?
- 17 A I don't have a number. Agencies such as
- 18 the Environmental Protection Agency have done
- 19 calculations, after all these are estimates, they're
- 20 statistical estimates. With some time, I could
- 21 derive a number, just as the Environmental Protection
- 22 Agency derives a number.
- 23 If you're asking for a specific number to
- 24 get kind of a ballpark, the numbers that are talked
- 25 about right now are somewhere around five percent, so

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- 1 they're about double what were in this.
- 2 Q Five percent? And what are the numbers
- 3 that are talked about for cigarettes for lung cancer?
- 4 A Well, again, in this particular case we're
- 5 talking about a woman who had not smoked for ten
- 6 years. I believe the number that you have on the
- 7 board there deals with the current smoking
- 8 population. So if in this particular case we were to
- 9 make a comparison, we'd want to compare the history

- 10 of the person that smoked who is not a current smoker
- 11 and hasn't smoked for a decade, with other risk
- 12 factors, such as air pollution and family history and
- 13 so forth, as I pointed out earlier.
- 14 Q I'm sorry, Dr. Thomas, I guess I wasn't
- 15 clear when I asked you. The statement that we just
- 16 looked at talked about the -- the amount of lung
- 17 cancer in the United States due to air pollution.
- 18 A Yes.
- 19 Q It said one to two percent.
- 20 A Yes.
- 21 Q All right. Now -- and you said, Well, now
- 22 that's up to five percent.
- 23 A Yes. Some people would estimate five
- 24 percent. I've seen some slightly higher, some
- 25 slightly lower, it depends on who --

- Q And what is the estimate --
- 2 A Excuse me, if I could finish?
- 3 Q Yes, go ahead.
- 4 A It depends on who is actually conducting
- 5 the estimate. I think people need to realize that
- 6 these are statistical estimates and vary depending on
- 7 who does them.
- 8 Q All right. And so what is the estimate for
- 9 the percentage of lung cancer in the United States
- 10 caused by cigarette smoking?
- 11 A You mean current smokers or previous
- 12 smokers?

- 13 Q The total amount of lung cancer, just like
- 14 the surgeon general says it.
- 15 A Well, the figure that you used up here this
- 16 morning was something along 40 to 50 percent.
- 17 Q Well, that wasn't the figure I used up
- 18 here, Doctor. That was the -- that's the risk for
- 19 each individual smoker.
- 20 My question now is of -- is of the total
- 21 amount of lung cancer in the United States, what is
- 22 the percentage due to cigarette smoking, if you know?
- 23 A This is a very general question. All
- 24 cancers? All lung cancers? Maybe you could be more
- 25 specific.

- 1 Q I said lung cancers.
- 2 A Oh, lung cancers?
- 3 Q Yes, I did.
- 4 A The numbers in the literature range, again
- 5 these are estimates, somewhere -- 80 percent, 85
- 6 percent, 90 percent. It depends on who does the
- 7 estimates. I've seen some as low as 70 percent.
- 8 Q Okay.
- 9 A And, of course, these are current smokers,
- 10 too.
- 11 Q Who is?
- 12 A Well, these estimates are based on
- 13 epidemiologic studies and the studies are done on
- 14 current smokers.

- 15 Q The estimates are -- Doctor, aren't they
- 16 for all of the lung cancers in the United States?
- 17 Doesn't that include smokers who are currently
- 18 smocking, smokers who have stopped and also people
- 19 who haven't ever smoked? Everybody. ?
- 20 A The total number of lung cancers includes
- 21 that, that's correct.
- Q Okay.
- 23 A But what I'm saying is the estimates that
- 24 are done for smoking are usually based on current
- 25 smokers. The reason, of course, is is that after

- 1 smoking stops, as we've talked about earlier, after
- 2 cessation, then the risks drops. So to try to
- 3 produce the least error as possible, they use current
- 4 smokers in these estimates.
- 5 Q So you've studed the decline and risk after
- 6 a person stops smoking?
- 7 A Yes, I've examined that issue.
- 8 Q And you have a looked at the 1990 surgeon
- 9 general report?
- 10 A Yes.
- 11 Q And, therefore, you're familiar with page
- 12 123, the -- a chart of relative risks versus years
- 13 since cessation; do you recognize that?
- 14 A Yes, I do.
- O So let's see if we can make some sense.
- 16 A I'm sorry, can you make it a little higher
- 17 so I can see what's below?

- 18 Q All right.
- 19 A Okay. Relative risks.
- 20 Q How many years since cessation is Mrs.
- 21 Karbinwnyk?
- 22 A At the time her cancer was diagnosed it was
- 23 11, 12 years.
- Q All right. So let's go over here. That's
- 25 10. Try to keep this straight, there's -- that would

- 1 be 11 to is 12 years right there?
- 2 A Yeah.
- 3 Q Make there. And there's two lines here, so
- 4 I'll make a mark on each one then we'll see what they
- 5 are. And then let's carry this one over to here and
- 6 this one over to here. See that?
- 7 A Yes.
- 8 Q Did I do that okay so far?
- 9 A Yeah.
- 11 lines?
- 12 A Well, the first -- the top line is with
- 13 adjustments for smoking duration. The bottom line is
- 14 without adjustments for smoking duration. And this
- 15 report's entitled Risks of Lung Cancer Among
- 16 Ex-smokers Compared with -- and I'm not sure if you
- 17 could move it up a little bit more, I could finish
- 18 reading it -- compared with cessation smokers as a
- 19 function of time since stopping smoking, estimated

- 20 from logistic progressions --21 Q Okay. The best I could read, it looks like it's a 22 log scale on this side. 23 24 0 Yeah. 25
 - A But basically what it shows -- okay. 3472 Karbiwnyk vs. R.J. Reynolds 10/23/97 1:00 p.m. - 2:50 p.m. ROUGH DRAFT Basically what it shows is a drop in relative risks 1 based on cessation of smoking. It's complicated the way they've presented it. There are easier ways of 3 presenting this information. 4 5 0 But --6 But it -- I mean, we're talking about drops 7 between those. 8 Well, if -- if -- following either -either line, let's follow the top line. How much is 9 the drop after 11 years? 10 11 This is relative risk, which means these are based on mortality, so it's not a very good 12 13 comparison with our current case since Mrs. Karbiwnyk was living and is in remission currently. 14 Could you ask me the question again? I'm still trying to understand quite what they've done. risk down the side. Q Yeah.

- 23 A And the relative risk is dropped after 12
- 24 years to, what, .85, I guess.
- Q Doesn't that show, Dr. Thomas, that

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- 1 according to that chart published by the surgeon
- 2 general, that after 11 years, a -- a person who stops
- 3 smoking 11 years later has come down to only 80
- 4 percent of the risk that they had when they stopped?
- 5 A No, it doesn't show that. In fact, this is
- 6 a log scale down the side. You'll notice how this
- 7 gets smaller as it comes down, so it makes these
- 8 numbers look larger. And this is also a relative
- 9 risk which means that this is a set of estimates
- 10 based on mortality using a linear regression method,
- 11 which I think actually tends to distort what's
- 12 happening up here and that's why you've got such
- 13 large bars. This is not the way I would represent
- 14 that information.
- 15 Q Whether you'd represent it or not, the
- 16 surgeon general has represented that information as
- 17 showing that after 10 years or 11 years of cessation,
- 18 that depending on which line you follow, whether you
- 19 adjust for smoking duration or you don't, you only
- 20 shed between 10 and 15 percent of the hazard that you
- 21 had when you stopped; isn't that true?
- 22 A Basically what happens -- well, let me try
- 23 to answer your question. The answer to your question
- 24 is yes, you shed about 15 percent, based on a log

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- 1 linear scale, it's a log scale. The risk is
- 2 injury --
- 3 A JUROR: Can you use another marker,
- 4 please? Can you use another marker, please?
- 5 That stuff's getting high, man. I've got a
- 6 headache.
- 7 THE COURT: I'm sorry, I was going to tell
- 8 him at lunch break but I forgot about it. I can
- 9 smell it up here sometimes.
- 10 A JUROR: I was getting a headache from
- 11 that.
- 12 THE COURT: I apologize. I meant to tell
- him to find something in the lunch break.
- 14 A JUROR: You used another one.
- THE COURT: Mr. Wilner, there's some
- 16 more --
- 17 A JUROR: I'm sorry, I didn't mean --
- 18 THE COURT: I'm glad you did.
- 19 MR. WILNER: This one smells okay.
- 20 THE COURT: I'm worried about what they
- think.
- MR. WILNER: Oh, I know, but I tested it.
- THE COURT: Okay.
- 24 A What I was saying when we had the problems
- 25 with the marker, was that these are mortality

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- 1 studies, so we're talking about mortality. And we're
- 2 also talking about the fact that -- this is a
- 3 complicated way to present this information. This
- 4 would -- this doesn't mean the information is wrong.
- 5 I was trying to think of an easy way to explain it.
- 6 BY MR. WILNER:
- 7 Q Well, Dr. Thomas, let me ask you a
- 8 question, maybe that will move it along.
- 9 A If I could finish --
- 10 MR. YOUNG: Objection, Your Honor. May he
- 11 finish his answer?
- 12 A If I can finish? I think an easy way to
- 13 think about this is that we all are going to die.
- 14 There's nobody that's born that's not going to die.
- 15 So what they're trying to do also is adjust the
- 16 curves based on increased mortality with time. In
- 17 other words, as you get older, your chances of dying
- 18 increase. And so the reason they presented it in
- 19 such a complicated way is they're trying to say,
- 20 Well, let's adjust for mortality of the whole
- 21 population and see what change it makes and that's
- 22 why it was also put on a log scale.
- 23 Log scales are difficult to understand.
- 24 I'm sure that you're having difficulty understanding
- 25 how this is being presented. There are easier ways

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ROUGH DRAFT

- 1 of presenting it.
- 2 Q Dr. Thomas, just -- not to quibble, Dr.
- 3 Thomas, this is a chart that -- that the surgeon
- 4 general provided in his text in 1990; is that
- 5 correct? Do we all agree on that?
- 6 A Yes.
- 7 Q And it shows, regardless of your feeling
- 8 about the scale and so forth, that people who stop
- 9 smoking even after 11 years later still have between
- 10 85 and 90 percent of the risks they had when they
- 11 stopped?
- 12 A But what they're also taking --
- 13 Q First answer my question before you say
- 14 but. Yes or no?
- 15 A Yes.
- 16 Q Okay. Thank you. Now you can explain.
- 17 A What they're basically saying, though, is
- 18 that as the person gets older, their mortality
- 19 increases.
- 20 Q Thank you.
- 21 A So that's taking into consideration the
- 22 increased mortality at the same time the risk is
- 23 dropping off, so this is trying to subtract the two.
- Q Okay. All right. Just a few more things,
- 25 if I could and then we'll really be gone. All

- 1 right. Back to the Premier study for a question or
- 2 two. That was tab 35 if you want to see it. I'll
- 3 try to do my best to represent it to you on the

- 4 screen. And that's everything there is on the
- 5 document.
- 6 A Why don't I just look at the screen.
- 7 Q Fine. This -- this is a part of the
- 8 Premier study that shows an analyses of various parts
- 9 of smoke; do you see that?
- 10 A Yes.
- 11 Q And part of those or two of those -- those
- 12 are called NNN and NNK; do you you see that?
- 13 A Yes.
- 14 Q And they are in nanograms per cigarette,
- 15 correct?
- 16 A Yeah, nanograms per cigarette.
- 17 Q And the control is given as -- with a
- 18 number and the new is given and the new one is much
- 19 smaller; you see that?
- 20 A This is the new?
- 21 Q Right.
- 22 A Okay. Where's the control on this?
- Q That's the control.
- 24 A I'm sorry. My eyes aren't that good.
- 25 Q The one beside the small one, that's the

- 1 control.
- 2 A This is the control?
- 3 Q That's right.
- 4 A Yeah. It's hard to tell. Okay.
- 5 Q Now, are you familiar with -- with

- 6 published values -- well, before I ask you that, you
- 7 see that word TSNA?
- 8 A Yes.
- 9 Q What does TSNA mean?
- 10 A I'm not sure how they're using it here. It
- 11 has several meanings.
- 12 Q Give us a couple.
- 13 A Well, total suspended nitrates and
- 14 nitrogen-containing compounds in alcohol solution is
- one that it means. TSNA has several different
- 16 meanings. I'd have to know what you're talking
- 17 about.
- 18 Q Well, what is NNN and NNK?
- 19 A These are N-Nitroso compounds, and this is
- 20 often referred to nitroso compound suspened in
- 21 alcohol.
- 22 Q In fact, it refers to tobacco specific
- 23 nitrosamines, doesn't it?
- 24 A I don't know. That's what you're telling
- 25 me.

- 1 Q All right. You haven't heard that? So
- 2 tell us what NNN and NNK are.
- 3 A Well, again, those are N-Nitrosonicotine.
- 4 These are both N-Nitroso compounds that are found in
- 5 nicotine.
- 6 Q And actually they're the result of the
- 7 nitrosation -- Nitroso -- a reaction of nicotine in
- 8 cigarettes causes those things to occur, right?

- 9 A Yeah, basically that's how they occur.
- 10 It's -- they react as a nitrate within the -- the
- 11 tobacco to form the N-Nitroso compounds.
- 12 Q You're familiar with the 1979 surgeon
- 13 general's report?
- 14 A Yes, I am.
- 15 Q You've ever seen the diagrams where
- 16 nicotine is -- produces NNN and NNK?
- 17 A Yes, I am familiar with that.
- 18 Q And you know, then, that NNN and NNK are
- 19 referred to as powerful organ-specific carcinogens?
- 20 A Yes. They're part of a class of materials,
- 21 the N-Nitroso compounds, several of which have found
- 22 to be carcinogenic.
- 23 Q And the amount of nitrates and nicotine in
- 24 tobacco relates to the amount of NNN and NNK in the
- 25 smoke?

- 1 A It may or may not. The problem with the
- 2 N-Nitroso compounds in doing these types of analyses,
- 3 is that N-Nitroso compounds are very reactive
- 4 materials. They are formed and often react within
- 5 seconds after being formed. So it's depending a lot
- 6 on what the conditions are in the cigarette, whether
- 7 you actually have it in the smoke or not, or whether
- 8 it's in the cigarette or not.
- 9 And I've done analysis of these compounds
- 10 specifically in different materials, and even the

- 11 same material from day-to-day, they would vary a
- 12 great deal depending on what the conditions are. So
- 13 I can't answer your question just because these are
- 14 such reactive materials.
- I do know, though, that they occur in
- 16 cigarettes at very low concentrations.
- 17 Q And do you know whether in these very low
- 18 concentrations they're very, very dangerous in
- 19 cigarettes?
- 20 A No, I don't know that.
- 21 Q Do you know the work -- do you know who
- 22 Detrich Hoffmann is?
- 23 A Yes, I do.
- Q And you recognize him as a leader in the
- 25 field of analysis of cigarettes and smoke concentrate

- 1 or -- smoke chemistry, right?
- 2 A Yeah, he's published extensively in the
- 3 area.
- 4 Q And he has analyzed these NNN and NNK
- 5 actors in cigarettes to see how dangerous they might
- 6 be, true?
- 7 A He's done analysis of these, yeah.
- 8 Q Well, let me hand you an article that he's
- 9 written and I'll ask you a few questions about it.
- 10 It's called The Changing Cigarette, it was in -- and
- 11 since -- I just want to take a moment and read you
- 12 the abstract and then ask you if you agree or not
- 13 with various statements in it. Let me put it up.

- 14 It begins by saying, nicotine is recognized 15 to be the major inducer of tobacco dependence. The 16 smoking of cigarettes as an advantageous delivery 17 system for nicotine accelerates and aggravates 18 cardiovascular disease and is causally associated with increased risk for chronic obstructive lung 19 20 disease, cancer of the lung and the upper air 21 digestive system and cancer of the pancreas, renal pelvis and urinary bladder. It is also associated 2.2 23 with cancer of the liver, cancer of the uterine 24 cervix, cancer of the nasal cavity and myeloid
- 25 leukemia. 3482 Karbiwnyk vs. R.J. Reynolds 10/23/97 1:00 p.m. - 2:50 p.m. ROUGH DRAFT And before we get to the NNN and NNK, do 1 2 you agree with that? Statistically, which is what he's referring 3 4 to, there certainly are statistical associations, as 5 he said increased risks of, and he lists several 6 things. 7 Cancer of the pancreas, renal pelvis. I think the renal pelvis is -- there's some debate 9 still ongoing about renal pelvis. That may or may not be. 10 11 Urinary bladder is also one that's being
- Well, there's other statistical
 associations in some epidemiologic studies with the
 liver.

debated currently.

- The one for uterine cervix is probably
- 17 not. Cancer of the nasal cavity --
- 18 Q Well, let's focus on the lung.
- 19 A Well, you asked me about this paragraph.
- 20 O All right.
- 21 A I'm just going through. Some of them I
- 22 could agree with, some I couldn't.
- 23 Q All right. And you stayed statistically,
- 24 does this doctor say causally associated?
- 25 A Well, yeah. He's talking about statistical

- 1 associations.
- 2 Q You know that?
- 3 A Well, that's the way its being used here.
- 4 He says increased risks of, he's talking about
- 5 statistical risks.
- 6 Q Let's go on. Now, before we go down to NNN
- 7 and NNK, I want to ask you about the first sentence.
- 8 It says, Nicotine is recognized to be the
- 9 major inducer of tobacco dependence. Is the dose of
- 10 a carcinogen, according to you, critical in
- 11 evaluating its response?
- 12 A Yes, it is.
- 13 Q And do you agree that nicotine is a
- 14 regulator of dose in cigarettes?
- 15 A I don't know what you mean by regulator of
- 16 dose.
- 17 Q You don't know whether nicotine influences
- 18 the dose, the amount of smoking that people do?

- 19 A I haven't gone back and looked at
- 20 information specifically on nicotine. I was asked to
- 21 look at materials concerning carcinogenicity. Well,
- 22 I know that nicotine is in cigarettes.
- 23 Q And do you agree or disagree that nicotine
- 24 is recognized to be the major inducer of tobacco
- 25 dependents?

- 1 A Like I say, I haven't looked at that. I
- 2 see in the newspaper, as others do, these types of
- 3 statements. But as a scientist, I haven't gone back
- 4 and read the studies myself to agree or disagree with
- 5 that statement. I simply don't know.
- 6 Q Certainly is a critical issue in terms of
- 7 the amount of dose of carcinogens that people might
- 8 get, isn't it?
- 9 A I don't know how to answer that since that
- 10 assumes that it is.
- 11 Q Let's go on. In 1950, the first
- 12 large-scale epidemiological studies documented that
- 13 cigarette smoking induces lung cancer and described a
- 14 dose response relationship between the number of
- 15 cigarettes smoked and the risks for developing lung
- 16 cancer; do you agree?
- 17 A It was 1950 that the first five
- 18 epidemiologic studies were conducted and they did see
- 19 dose response relationship. I generally agree with
- 20 that.

- 21 Q In the following decades these observations
- 22 were not not only confirmed by several hundreds of
- 23 prospective and case-control studies but the
- 24 plausibility of this causal association was also
- 25 supported by bioassays and by the identification of

- 1 carcinogens in cigarette smoke; do you agree?
- 2 A Well, he's talking about a statistical
- 3 association again. And he says that there is some
- 4 supporting information in bioassays and other
- 5 information. It's true there is some supporting
- 6 information.
- 7 Q Again you're putting words in about a
- 8 statistical association. Doesn't he say a causal
- 9 association? Whatever that is.
- 10 A From the previous paragraph, it was clear
- 11 that he was talking about the statistical association
- 12 because he said increased risks of.
- 13 Q And when it says, Supported by bioassays in
- 14 the identification of carcinogens in cigarette smoke,
- 15 you agree that support has been there?
- 16 A There have been a lot of studies done
- 17 throughout the last 30, 40 years, certainly in the
- 18 hundreds. Some of them are supportive and some are
- 19 not supportive.
- 20 Q Whole smoke induces lung tumors in mice and
- 21 tumors in the upper respiratory tract of hamsters; do
- 22 you agree?
- 23 A I disagree with that.

- Q He's wrong?
- 25 A Most scientists, including myself, that

- 1 have reviewed these have shown these not to be the
- 2 case, including the surgeon general.
- 3 Q The particulate matter of the smoke elicits
- 4 benign and malignant tumors of the skin in mice and
- 5 rabbits, sarcoma in the connective tissue of rats,
- 6 and carcinoma in the lungs of rates upon
- 7 intratracheal instillation; do you agree?
- 8 A Well, let's see, I agree -- I have to read
- 9 these to see what he's talking about since this is a
- 10 -- a summary statement as an introduction. He's
- 11 talking about skin painting, and skin painting has
- 12 been conducted on mice and rabbits and we've seen
- 13 tumors conducted from skin painting.
- 14 The intratracheal instillation, there has
- 15 not been a successful method of really doing that so
- 16 I disagree with the rest of that.
- 17 We have seen malignant tumors certainly in
- 18 the skin of mice, but a lot of these methods --
- 19 intratracheal instillation actually is not used any
- 20 more because it's considered not to really be useful
- 21 experimental technique.
- Q More than 50 carcinogens have been
- 23 identified, including the following classes of
- 24 compounds polynuclear aromatic hydrocarbons, PAH,
- 25 aromatic amines, and N-Nitrosamines. Among the

- 1 latter, the tobacco-specific N-Nitrosamines, TSNA,
- 2 have been shown to be of special significance; do you
- 3 see that?
- 4 A Yes, I see that.
- 5 Q Do you agree?
- 6 A Well, out of a thousand materials or
- 7 chemicals that have been identified in tobacco smoke,
- 8 I'm sure there's at least 50 that have been
- 9 identified by one or another group to be carcinogenic
- 10 based on their definitions. So the definition may be
- in animals only or in humans or in both.
- 12 Let's see, the last part of this, we were
- 13 talking this morning about polynuclear aromatic
- 14 hydrocarbons, those are produced during combustion,
- 15 and you find those -- you find the others as well,
- 16 however at very low concentrations.
- 17 Q Do you agree that the TSNA, the
- 18 tobacco-specific N-Nitrosamines have been shown to be
- 19 of special significance?
- 20 A I don't know what he means by that
- 21 statement. I don't know what he's saying.
- 22 Significance for what?
- 23 Q All right. Since 1950, the makeup of --
- oh, you don't know what it's significant for?
- 25 A No, I don't know.

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- 1 Q Is that what you said?
- 2 A Yeah. Special significance for what?
- 3 Q For cancer.
- 4 A Well's, he was talking about a hosts of
- 5 different diseases earlier. I just -- you know, it's
- 6 a very general statements. I don't know what it's
- 7 about. I have to read the article.
- 8 Q Since 1950, the makeup of the cigarettes
- 9 and the composition of cigarette smoke have gradually
- 10 changed. In the United States the sales-weighted
- 11 average tar and nicotine yields have declined from a
- 12 high of 38 milligrams tar to 2.7 milligrams of
- 13 nicotine in 1954 to 12 milligrams and 0.95 milligrams
- 14 in 1992, respectively. In the United Kingdom, the
- decline was from about 32 milligrams of tar and 2.2
- 16 milligrams of nicotine to less than 12 milligrams of
- 17 tar and 1.0 milligrams nicotine per cigarette.
- 18 During this same time, other smoke constituents
- 19 changed correspondingly. These reductions of smoke
- 20 yields were primarily achieved by the introduction of
- 21 filter tips, with and without perforation and it goes
- 22 on to say some different changes involved in the
- 23 cigarette.
- 24 Are you familiar with those in general or
- is that outside your area of expertise?

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1 A The numbers that are shown here, I

- 2 certianly can't verify the numbers, but they are the
- 3 types of numbers I've seen in other publications, and
- 4 know I know in what I read there have been various
- 5 attempts to try to reduce some of these materials.
- 6 Q Then he goes on to say, More complete
- 7 combustion decreases the carcinogenic PAH, yet the
- 8 increased generation of nitrogen oxides enhances --
- 9 A I'm sorry, where are you reading? You've
- 10 lost me again.
- 11 Q At the bottom of that paragraph more
- 12 complete combustion --
- 13 A Okay.
- 14 Q More complete combustion decreases the
- 15 carcinogenic PAH, yet the increased generation of
- 16 nitrogen oxides enhances the formation of
- 17 carcinogenic N-Nitrosamines, especially the TSNA in
- 18 the smoke. Did you know that?
- 19 A Okay. So he's saying as the combustion
- 20 decreases the polycyclic aromatic hydrocarbons and
- 21 increases the generation of nitrogen oxides -- I've
- 22 seen others that have made those type of statements.
- 23 I haven't looked into that issue. I don't know if
- 24 that's the case or not.
- 25 Q Do you know whether the carcinogenic

- 1 tobacco-specific N-Nitrosamines, these TSNAs, have
- 2 been going up in cigarettes?
- 3 A Well, like I say, I've seen reports that
- 4 there are increases in some cigrettes, there's also

- 5 degreeses in others. It really depends on how the
- 6 cigarette is designed.
- 7 As I indicated, these chemicals are very
- 8 reactive chemicals and don't exist for very long time
- 9 periods, so a lot of it has to do with how the
- 10 cigarette is designed.
- 11 And -- so he's made a fairly sweeping
- 12 statement here which I would be surprised that it
- 13 would apply to all cigarettes.
- Q Well, do you have any reason to think that
- 15 Winston cigarettes are different?
- 16 A I'm not talking about Winston cigarettes.
- 17 I said all cigarettes. And based on what I know
- 18 about N-Nitroso compounds, having work on them for
- 19 many years, I know they are very susceptible to
- 20 changes, so I would expect to see changes .
- 21 Q Let's read the last conclusion of this
- 22 statement, if we might. The overview -- which is, I
- 23 guess, this paper -- also discusses furnished needs
- 24 for reducing the toxicity and carcinogenicity --
- 25 A I'm sorry, are you on the next page?

- 1 Q No, I'm sorry, it's the bottom of that
- 2 page.
- 3 A It's the next page on my copy.
- 4 Q The overview also discusses further needs
- 5 for reducing the toxicity and carcinogenicity of
- 6 cigarette smoke. From a public health perspective,

- 7 nicotine in the smoke -- in the smoke needs to be
- 8 lowered to a level at which there is no induction of
- 9 dependence on tobacco; do you see that?
- 10 A Yes, I see that.
- 11 Q Do you agree?
- 12 A That that's what he discusses in his paper?
- 13 Q No, from a public health perspective,
- 14 that's what has to be done?
- 15 A Well, that's not what he says here. He
- 16 says -- this is -- this is an overview. He's
- 17 describing what he's discussing in his paper. He
- 18 discusses further needs for this and that and the
- 19 other. There's nothing to agree with or disagree.
- 20 I'd have to read the paper --
- 21 Q All right. Let me ask you this statement
- 22 then --
- 23 A -- To get an understanding of this paper .
- Q Let me ask you this statement then. Let's
- 25 read the very last statement and then I'll ask you if

- 1 you agree or disagree. From a public health
- 2 perspective, nicotine in the smoke needs to be
- 3 lowered to a level at which there is no induction of
- 4 dependence on tobacco. From a public health's
- 5 perspective.
- 6 Do you agree or disagree from a public
- 7 health perspective?
- 8 MR. YOUNG: Objection, Your Honor, he
- 9 testified he hasn't read the paper.

10	THE COURT: I agree, Mr. Wilner. How is he
11	supposed to answer it?
12	MR. WILNER: Well, I don't know, he's given
13	opinions here today, Your Honor, about the
14	relative risks of cigarettes. And I I guess
15	if he has no opinion, then he has no opinion. I
16	don't know.
17	THE COURT: Proceed.
18	A Like I say, I haven't gone back and looked
19	at the nicotine literature and I really couldn't draw
20	an opinion on this. It would just be speculation.
21	Q You don't have an opinion one way or the
22	other?
23	A I haven't reviewed the issue. I haven't
24	even read the paper he's talking about that this is
25	an overview of.
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1	Q Okay.
2	MR. WILNER: Thank you for being patient
3	with me, Dr. Thomas. I have no further
4	questions.
5	THE COURT: Thank you. Mr. Young?
6	MR. YOUNG: May I have five minutes, Your

THE COURT: Ladies and Gentlemen, if you

will step in the jury room, we will be in a

THE COURT: Sure.

MR. YOUNG: Thank you.

7 Honor?

8

9

10

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12
         short recess.
13
              (Short recess.)
              THE COURT: Are you ready, Mr. Young?
14
              MR. YOUNG: Yeah.
15
              THE COURT: All right. Let's come to
16
         order, please. Bring out the jury.
17
               (The jury was seated in the jury box and
18
19
         the following was held in open court:)
              THE COURT: All right. Be seated, Ladies
20
21
         and Gentlemen. Mr. Young?
              MR. YOUNG: Thank you, Your Honor.
2.2
23
                     REDIRECT EXAMINATION
    BY MR. YOUNG:
24
        O Dr. Thomas, Mr. Wilner had you talk about
25
                                                    3494
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    some numbers with respect to an air pollution study
2
    done in the Kanawha Valley sometime in the '80s; do
3
    you recall that?
             Yes, I do.
 4
         A
5
              And part of that calculation involved a 50
    percent lifetime risk for smoking; is that right?
6
         A That actually wasn't in that particular
7
    study. That was taken out of, I think, the surgeon
9
    general's information. But he was making a
10
    comparison with the Kanawha Valley study.
             Okay. And with respect to that 50 percent
11
    number, putting aside whether you agree that that's a
12
    valid number or not, for what status of smokers is
13
14
    that 50 percent figured on?
```

- 15 A Again, as I mentioned before, that's based
- on the epidemiologic studies, and these studies are
- 17 conducted on current smokers, so it's really based on
- 18 mortality, if you will.
- 19 Q And not former smokers?
- 20 A No, not former smokers. The risks are
- 21 simply too low in former smokers.
- Q Now, you also made a calculation or Mr.
- 23 Wilner made a calculation of 1/10th of 1 percent
- 24 lifetime risk for air pollution; do you remember
- 25 that?

- 1 A Yes, I do.
- 2 Q And that was based on an EPA study of the
- 3 Kanawha Valley that I think you said you were
- 4 familiar with?
- 5 A Yes.
- 6 Q And about when was that study conducted?
- 7 A That was conducted about 1987, '88.
- 8 Q And was that a risk assessment study?
- 9 A Yes, that was a risk assessment study.
- 10 $\,$ Q $\,$ And was the risk based upon the level of
- 11 air pollution in the Kanawha Valley back at the time
- 12 that Mrs. Karbiwnyk lived there?
- 13 A No, it was not.
- 14 Q What was that risk calculated on?
- 15 A That was calculated on current levels in
- 16 1988, 1989, which would have been much lower than the

- 17 levels during the time that she grew up there.
- 18 Q And did anything happen in terms of the
- 19 control of air pollution in the Kanawha Valley
- 20 between 1957, when Mrs. Karbiwnyk left, and in the
- 21 1980s when that study was conducted?
- 22 A Well, the first air pollution laws in the
- 23 United States were instigated in the early 1960s, and
- 24 as I think everybody's aware, they continued to get
- 25 more strict and factories of various concerns had

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- 1 been required to reduce their air pollution by 90
- 2 percent, 95 percent. There have been extensive
- 3 reductions in air pollution over that time period.
- 4 Q And I too want to be abundantly fair with
- 5 you, do you think that the risk assessed in that EPA
- 6 study realistically assesses the risk that was in
- 7 existence for the time period Mrs. Karbiwnyk lived in
- 8 Charleston?
- 9 A No.
- 10 Q Let me also call your attention to the
- 11 Premier study that was brought into evidence.
- MR. YOUNG: Mrs. Kent, do you have that
- 13 figure?
- Q Up on the TV screen, can you see that?
- MR. YOUNG: Can we back away a little bit,
- 16 Mrs. Kent?
- 17 A Yeah, if I could use the monitor?
- 18 Q Please.
- 19 A It's easier for me. Yes.

- 20 Q This is a 90-day inhalation study, right?
- 21 A Yes, that's correct.
- 23 A In a rat.
- Q Okay. And this indicates it produced
- 25 squamous sell metaplasia of the larynx; is that

- 1 correct?
- 2 A That's right.
- 3 Q Or the test was designed to check on, or
- 4 can't you tell?
- 5 A You can't really tell from this. This
- 6 appears to be something that was used in a
- 7 presentation, maybe a summary to scientists. And
- 8 this is somebody's summary that they have on one
- 9 page. So this don't really tell me very much about
- 10 the study other than it was a 90-day study done on
- 11 rats. And one of the findings seemed to be squamous
- 12 cell metaplasia but it doesn't tell me anything else
- 13 about the study.
- 14 Q Is squamous cell a form of lung cancer?
- 15 A No, it's not.
- Q Well, is squamous -- is there such a thing
- 17 as squamous cell lung cancer?
- 18 A Yeah, there's squamous cell lung cancer.
- 19 Q Okay. Is that the kind of lung cancer Mrs.
- 20 Karbiwnyk has?
- 21 A No, it's not.

Q Is there something called squamous cell
metaplasia?

A Yes, that's a pathological description of

changes within, in this case, the larynx.

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- 1 Q Is squamous cell metaplasia cancer?
- 2 A No, it's not.
- 3 Q Is the disease at issue in this lawsuit
- 4 cancer of the larynx?
- 5 A No, it's not.
- 6 MR. YOUNG: Mrs. Kent, do you have another
- 7 overhead.
- 8 Q Why don't you stay there, Doctor. This is
- 9 the other inhalation study that was put up on the
- 10 hamster?

- 11 A Yes.
- 12 Q And does that also refer to squamous cell
- 13 metaplasia of the larynx?
- 14 A Yes, it does.
- 15 Q Thank you. You can return to your seat.
- Now, you were also shown a chart from the
- 17 1990 surgeon general report, do you recall that?
- 18 A Yes, I do.
- 19 MR. YOUNG: Is that available? Woody, do
- 20 you still have that?
- MR. WILNER: It's in the surgeon general
- 22 report, just a minute. I can't remember where I
- 23 put the surgeon general report.
- MR. GROSSMAN: Is it this one?

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MR. YOUNG: Never mind.

- 2 BY MR. YOUNG:
- 3 Q Do you remember the chart, Doctor?
- 4 A Yes, I do.
- 5 Q You mentioned some concern about the chart,
- 6 do you recall that?
- 7 A Yes.
- 8 Q One of the concerns you mentioned was that
- 9 it was a mortality study?
- 10 A That's right.
- 11 Q What does that mean?
- 12 A Well, that means that the chart was based,
- 13 again, on mortality studies. And in the case that
- 14 we're talking about, this is a person that's alive
- 15 and in remission. So we're applying studies for
- 16 people that have died compared with somebody that's
- 17 still alive, so there's not as much of an
- 18 application.
- 19 Q A mortality study is a death study; is that
- 20 right?
- 21 A That's right.
- Q Do you consider it fair when you're trying
- 23 to calculate the risk for a former smoker to look at
- 24 the death date and to compare that to the diagnosis
- 25 date? Maybe my question --

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- Yeah. I'm not sure I understand your 1
- 2 question.
- Okay. Do you think it's fair to use a 3
- 4 mortality study for a living person?
- No, it's not. 5 Α
- Why is that? 6 Q
- 7 Well, because there's -- again, the
- statistics are based on death and represent all those 8
- steps leading up to death, whereas in a person that's
- 10 alive and living and in remission, the steps are very
- different. So it's not -- so it's like comparing 11
- 12 apples and oranges.
- Now, you -- you also mentioned some 13
- 14 problems with respect to a log scale.
- 15 A Yes.
- 16 Can you tell us about that problem?
- 17 Α The log scales are sometimes used to
- 18 represent data when to put it on a regular graph in a
- 19 linear manner, the graph would be as tall as the
- 20 ceiling. So what they do is to shrink it down where
- 21 you can get it on a page of a scale rather than put
- it on a linear scale, they put it on a log scale so 22
- 23 each section in the log represents a factor of 10.
- 24 And so going from one to the next is 10 times as
- 25 much, and the next to the next is 10 times as much.

- 1 And that was the problem in trying to interpret that
- 2 information, it's not to say that it's wrong
- 3 technically, it's just the way it's presented it
- 4 makes it difficult to analyze actually what has been
- 5 done because it's been compressed.
- 6 And the second thing that they tried to do
- 7 in that, which also had to do with the scale, is to
- 8 take into consideration life span and mortality in
- 9 people that don't smoke and people that do smoke
- 10 because it is mortality again.
- 11 Q Okay. Well, that -- well, that all dealt
- 12 with the issue in reduction of risk after a person
- 13 stopped smoking, right?
- 14 A That's correct.
- 15 Q And that was from the 1990 surgeon general
- 16 report, right?
- 17 A Yes.
- 18 Q And are you familiar with that report?
- 19 A Yes, I am.
- 20 Q And have you also read other studies about
- 21 reduction in risk?
- 22 A Yes. There are several epidemiologic
- 23 studies that have been conducted to look at this very
- 24 issue, and that's currently the approach the public
- 25 health officials use in the United States to reduce

- 1 risks so they want to make sure that they're doing
- 2 the right thing. So a lot of studies have been

- 3 conducted to measure reduction in the risk based on
- 4 smoking cessation or stopping smoking.
- 5 Q Well, what is -- just tell us, what's the
- 6 net effect of having -- of smoking cessation for more
- 7 than 10 years based upon all the different studies
- 8 that you've read?
- 9 A Well, as I mentioned, I believe it was this
- 10 morning, some studies show that after 10 years that a
- 11 smoker's risks drop back to the same level as a
- 12 nonsmoker. Some studies show that there's a slight
- increase over the nonsmoker.
- 14 Again, if you look at the nonsmoking
- 15 population, you see lung cancer, too, which is also
- 16 increasing with age, and that's what they were trying
- 17 to correct for on that table.
- 18 But I think to make it simple is that the
- 19 -- the values that I've seen have somewhere between
- 20 a risk of zero after 10 years above a nonsmoker to
- 21 twice background, which would be 2(x) or twofold over
- 22 background, so it would be twice as much risk as a
- 23 person who didn't smoke.
- Q And those are based upon what are called
- 25 epidemiological studies; is that correct?

- 1 A That's correct.
- 2 Q Can you do an epidemiological study to
- 3 compare individual brands of cigarettes?
- 4 A No, you can't.
- 5 Q Now, there was a reference made to in-vivo

- 6 and in-vitro tests; do you remember that?
- 7 A Yes.
- 8 Q And what are those two types of test?
- 9 A Generally in-vitro tests first are the ones
- 10 that are done on single cells that are grown in Petri
- 11 dishes in what's called a culture media. The in-vivo
- 12 studies are done in whole animals. Now, as I
- 13 mentioned, there's some crossover between between the
- 14 two but generally that's what they mean.
- 15 Q And have there been the -- the in-vivo
- 16 tests done on cigarette smokers?
- 17 A Yes.
- 18 Q For about how long?
- 19 A Well the first in 75 in-vivo inhalation
- 20 studies were done -- we first started seeing them
- 21 published in the early 1960s, and they extended
- 22 through about -- I think the last one was published
- 23 in 1984.
- Q And did those demonstrate to you that
- 25 cigarette smoking is a cause of lung cancer?

- 1 A No. Those laboratory animal studies were
- 2 all negative.
- 3 Q Now, as a toxicologist, you have conducted
- 4 inhalation experiments, is that right?
- 5 A Yes.
- 6 Q And you've reviewed the literture on
- 7 inhalation experiments?

- 8 A Yes, I have.
- 9 Q Have these -- have there been extensive
- 10 efforts to induce lung cancer in laboratory animals?
- 11 A Yes, there have been.
- 12 Q And what has been the results of those?
- 13 A The results have generally been negative.
- 14 And these have been reviewed, for example, in the
- 15 surgeon general's reports that we've been talking
- 16 about, and he's also indicated are generally negative
- in producing lung cancer within laboratory animals.
- 18 Q Let's also now switch and talk about these
- 19 FDA risk assessments. Does the FDA have a safety
- 20 criteria for cigarettes?
- 21 A No, it doesn't.
- Q Does the FDA set safety criterias typically
- 23 for consumer products?
- 24 A Probably the only real products that would
- 25 fall under that maybe would be pharmaceuticals, but

- 1 for what people would say are consumer products,
- 2 that's a different agency. The Consumer Product
- 3 Safety Commission has responsibility for those type
- 4 products.
- 5 Q Well, if you were to use risk assessments,
- 6 as the FDA does, would something like a ski be able
- 7 to pass?
- 8 A No.
- 9 Q How about a steak?
- 10 A You mean a beef steak?

```
11
          Q
               Right, a nice -- nice choice T-bone steak?
12
         Α
               It probably would not pass.
13
         0
               How about whiskey?
14
          Α
               Whiskey certainly wouldn't pass.
15
          Q
               How about wine?
               Wine wouldn't.
16
         Α
17
          Q
               How about?
18
         Α
               Some wines may.
              How about oysters?
19
          Q
20
         Α
               Raw oysters would not.
21
         Q
               How about aspirin?
22
         Α
               Aspirin would not. And that's an
23
     interesting one because there have been several
    studies published where they've actually taken
24
25
     aspirin through the criteria and showed that it would
                                                     3506
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 1
    fail.
               Speaking of consumer products, who
 2
     traditionally makes the utility determination on the
 3
 4
    use of a consumer product?
 5
         A
             In our form of government, in the end it's
 6
     the consumer that's supposed to make that decision.
 7
          0
              And let me ask you one final question. To
 8
     a reasonable degree of scientific likelihood, do you
 9
    believe that smoking more likely than not caused Mrs.
```

MR. YOUNG: Thank you.

Karbiwnyk's can lung cancer?

No.

A

10

11

13	THE COURT: Mr. Wilner, followups?
14	RECROSS EXAMINATION
15	BY MR. WILNER:
16	Q You said your last statement was that
17	smoking caused Mrs. Karbiwnyk's lung cancer. Does
18	smoking cause has smoking caused lung cancer in
19	any person in the United States?
20	A Statistically speaking we have
21	epidemiologic studies that confirm major increases in
22	the rate of cancer in smokers from a scientific
23	sense, which is what we were talking about,
24	laboratory animal studies, the answer is no.
25	Q So your answer is no to anyone in the
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1	United States, not just Mrs. Karbiwnyk?
2	A What I'm talking about actually is in the
3	case of Mrs. Karbiwnyk, we based on Dr. Gould's
4	testimony yesterday, the form of tumor that she has
5	is not generally even associated with cigarette
6	smoke, and she has several other risk factors. And I
7	was asked to draw a conclusion based on the risk
8	factors and the pathology of the tumor that we think
9	she had.
10	Q How about according to all the records at
11	Baptist Hospital, did you look at any of those?
12	MR. YOUNG: Objection, this is beyond the
1.0	
13	scope of redirect.
13	scope of redirect. MR. WILNER: He just he just answered

- 16 basis for that. He was --
- 17 THE COURT: The question that led to that
- answer was within cross, but go ahead, Mr.
- 19 Wilner
- 20 BY MR. WILNER.
- 21 Q You based your belief on the kind of cancer
- 22 that Joann Karbiwnyk has on what you were told about
- 23 the testimony of a witness here?
- 24 A And the medical records and the information
- 25 that I know about neuroendocrin tumors. I've seen

- 1 neuroendocrin tumors for several years.
- 2 Q And you saw that her doctors at Baptist
- 3 diagnosed her lung cancer as a small cell?
- 4 A They actually didn't diagnose it as a small
- 5 cell. As I remember, the pathology report said that
- 6 it was consistent with a small cell. They didn't say
- 7 it was a small cell.
- 8 Q The only one you saw said consistent with,
- 9 you didn't see the one that says small cell?
- 10 A Well, afterwards, that was what was quoted
- 11 based on a pathology report. But I -- again I would
- 12 look at the actual pathology report and try to
- 13 understand that. And it said it was consistent with,
- 14 in other words, it had some of the characteristics of
- 15 small cell.
- 16 Q And so your testimony is that the Gould
- 17 cancer is not related to smoking?

```
18
              It's -- I didn't say it was not related to
    small --
19
              MR. YOUNG: Objection, Your Honor.
20
              THE COURT: Mr. Wilner, this is outside --
21
              MR. WILNER: Your Honor may I? He just
22
         asked for his conclusion about whether her
23
         cancer is related to smoking, and this is --
24
25
         this is directly following that. Your -- I
                                                    3509
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1
         don't know any other way to examine him except
         to ask him that question.
2
              THE COURT: Go ahead.
3
4
              MR. WILNER: May --
    BY MR. WILNER:
5
             Your testimony is -- is this Gould cancer
6
    called atypical carcinoid or well-differentiated
8
    endocrin tumor, whatever you want to call it, is not
    related to cigarette smoking?
             It's only weakly related or not related.
10
11
    It depends again on the study. We're talking about
    very low statistical risks. In most studies where
12
13
    they compare smokers and nonsmokers, the rate is the
14
    same.
15
              I believe in Dr. Gould's papers, in fact,
16
    he has looked at his medical center specifically at
    this issue, and has found a slight increase, but it's
17
    -- it's slight.
18
        Q And you saw his 1990 paper where 14 out of
19
20
    15 of -- of people who had this cancer were cigarette
```

- 21 smokers?
- 22 A I -- you'd have to show me what you're
- 23 referring to.
- Q Well, can you produce any of these
- 25 epidemiologic studies you keep talking about?

- 1 A Well, Dr. Gould testified --
- 2 THE COURT: Mr. Wilner --
- 3 MR. WILNER: Yeah.
- 4 THE COURT: -- no more about production of
- 5 things.
- 6 MR. WILNER: Your Honor -- all right, I'll
- 7 move on.
- 8 BY MR. WILNER:
- 9 Q You -- you mentioned the pathology report
- 10 just now and you said it -- it mentioned consistent
- 11 with?
- 12 A Yes.
- 13 Q Is this the one?
- 14 A Again I'll have to look at the monitor.
- MR. GROSSMAN: Would you identify that for
- us, Woody.
- MR. WILNER: This is the record of 4/25/95
- 18 transcribed 4/26/95 by Dr. Holland. This is the
- 19 biopsy.
- 20 A Yeah, this is not the one I was referring
- 21 to. Let's see. Even in this one -- I can't tell
- 22 from what you've got up here. This appears to be a

- 23 pathology report. This just says it was a small cell
- 24 type. The neuroendocrin tumors are small size types
- 25 of tumors, they're small tumors. And I think what

- 1 Dr. Gould was testifying about is that there's a
- 2 difference between one small cell type and another.
- 3 And all this says is it was a small cell type.
- I might mention, as a pathologist, these
- 5 are very difficult to diagnose because there -- it's
- 6 within the same class, these neuroendocrin tumors,
- 7 and they have a lot of the same characteristics so
- 8 they are difficult to interpret.
- 9 Q You've seen this chart many places, haven't
- 10 you, Doctor?
- 11 A Let me look at the other one. I've seen
- 12 this before. I don't know what it's out of.
- 13 Q You've seen it before, though, haven't you?
- 14 A I -- I do remember seeing this before. But
- 15 like I say, I don't remember what it was from.
- 16 Q Do you understand how it's put together?
- 17 A Yes, I understand how it's put together.
- 18 Q And you testified before that -- that there
- 19 are many risk factors for lung cancer?
- 20 A Yes.
- 21 MR. YOUNG: Objection, that's beyond the
- scope of recross -- or redirect.
- 23 O You testified in redirect that the risk
- 24 factor that air pollution was a risk factor for lung
- 25 cancer?

Karbiwnyk vs. R.J. Reynolds 10/23/97 1:00 p.m. - 2:50 p.m. ROUGH DRAFT A Yes, it is.